

GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS APPENDIX

Please read the Guidelines (pages 1 through 15) carefully and submit pages A-2 through A-7 and all required forms and safeguards, including questionnaires, research instruments, letters of consent, and approvals from authorized officials to the Human Subjects Review Board.

As of January 1st, 2014 all investigators must complete NIH or CITI training to conduct research at Ashland University. Certification must be completed within the last five years and verification must be attached to HSRB application. Print and attach to application verification of human subject protections in research training.

To be typed or word-processed

SEQUENCE OF RESEARCH PROTOCOL REVIEW

Student Directed Research (*Students work closely with your advisor*)

- A. **NIH or CITI training in human subject protections in research within 5 years (Attach both student and faculty advisor certificate of proof to application)**
- B. Discuss project with advisor and receive approval to proceed.
- C. Complete Human Subjects Review Board Application: Part I, Part II, Part III (Investigator must sign application.)
- D. Obtain advisor's signed approval and forward to:

Dr. Larry Bunce
Executive Director of Institutional Effectiveness
100 Founders Hall
Ashland University
Ashland, OH 44805

(**Signed applications may be scanned to hsrb-au@ashland.edu, this is our preferred method of submission.**)

After Proposal is received:

- A. Director assigns the proposal to the appropriate reviewer(s).
- B. Proposal is reviewed and returned to the Director.
- C. HSRB Chair reviews, signs letter and forwards status of research proposal to the student's advisor.

Faculty Research

- A. **NIH or CITI training in human subject protections in research within 5 years (Attach certificate of proof to application)**
- B. Complete Human Subjects Review Board Application (Part I, Part II, Part III)
- C. Forward proposal to Graduate School Office, 100 Founders Hall (or scan to hsrb-au@ashland.edu).

After Proposal is received by Graduate School Office:

- A. Director assigns the proposal to the appropriate reviewer(s).
- B. HSRB or review members review proposal and return proposal to Graduate School Office.
- C. HSRB Chair reviews, signs letter and forwards status of research proposal to faculty member.

If you have any questions, please contact:

Dr. Christopher R. Chartier, Chair
Human Subjects Review Board
Phone: (419) 289.5342
E-Mail: cchartie@ashland.edu

**HUMAN SUBJECTS REVIEW BOARD
PART I
APPLICATION FOR APPROVAL TO USE HUMAN SUBJECTS IN RESEARCH**

**Return the original typewritten application including Parts II and III to:
Director of the Graduate School
119 Andrews Hall**

**OR
(Signed applications may be scanned to hsrb-au@ashland.edu, this is our preferred method of submission.)**

PRINCIPAL INVESTIGATOR Jennifer L. Groman DEPARTMENT COE/Doctoral Studies & Advanced Programs
(typed name)

ADDRESS 257 College of Education EMAIL jpgroman@ashland.edu

CITY Ashland STATE OH ZIP 4469 PHONE (419) 651-2586

CO-INVESTIGATOR(S) _____
(typed name) (signature)
_____ (signature)

PROJECT TITLE The Creativity Project – Second Survey, Alumni Impact

BEGINNING DATE OF RESEARCH (MONTH/YEAR) January, 2019

ANTICIPATED ENDING DATE OF RESEARCH (MONTH/YEAR) March, 2019

IS THIS RESEARCH RELATED TO A GRANT? Y/N N X IF YES, GRANT NUMBER: _____

TYPE OF PROJECT

FACULTY RESEARCH:

EXTERNALLY FUNDED YES _____ AGENCY _____
NO X

STUDENT DIRECTED RESEARCH:

ADVISOR _____
THESIS _____ DISSERTATION _____ COURSE REQUIREMENT _____
COURSE # _____ PRACTICUM _____ OTHER (Please Specify) _____

I agree to follow the procedures outlined in this summary description and any attachments to ensure that the rights and welfare of human subjects in my project are properly protected. I understand that no contact may be initiated with subjects until I have received approval of these procedures from the HSRB and complied with any required modifications in connection with that approval.

Jennifer L. Groman Date January 23, 2019
(Signature of Principal Investigator)

APPROVAL OF FACULTY ADVISOR: Required for all students

(Signature of Advisor) Date _____

PRINTED NAME OF ADVISOR _____
ADDRESS/AFFILIATION _____
CITY A STATE OH ZIP 44805
PHONE _____ E-MAIL _____

**HUMAN SUBJECTS REVIEW BOARD
PART II: RESEARCH PROTOCOL**

TYPE OF REVIEW REQUESTED (Choose One)

NOTE: Regardless of type of review, all of Part II and Part III must be completed and submitted to the HSRB. Research may begin only after written approval of HSRB is obtained.

_____ **EXEMPTED** I (We) believe the current project is **EXEMPTED**. It meets category(ies) _____ from the list of six categories on pages 4-6 of the Guidelines.

In the space below, explain why you feel your research project meets the **EXEMPTED** provisions. Briefly detail all the categories that apply to your research. (Refer to the six categories that define exempt status).

 X **EXPEDITED** I (We) believe the current project meets the **EXPEDITED** classification. It meets category(ies) (1) from the list of thirteen categories on pages 6-8 of the Guidelines.

In the space below, explain why you feel your research project meets the **EXPEDITED** provisions. Briefly detail all the categories that apply to your research. (Refer to the thirteen categories that define expedited status).

I continue gathering information about Creative Thinking Ability for what I call The Creativity Project. In this project I investigate students gifted in Creative Thinking Ability in districts throughout Ohio, and ascertain specific ways teachers might identify, support, and foster creativity in children. This IRB Proposal (Second Project Survey of Alumni) asks graduates of the Ashland University Talent Development Program (endorsement and MEd) about their experience with and subsequent use of the content in EDIS 654, "Creativity for Teachers of the Talented." This course is unique in its scope, and is based on Dr. Jane Piirto's model of Creative Training. It is holistic in nature, and integrates personal creativity alongside application activities for the classroom in creativity. I am interested to know if teachers believe their own creative enhancement is related to their use of these creativity principles in the classroom and how it is related.

Topics in each part of the survey are listed below.

Part I – Non-identifying demographic information (home district type, their role in the district, no district names are requested).

Part II – Short answer response prompts about their experience with EDIS 654 and their work in creativity (professionally or personally) since taking the course.

Participants will be invited to participate in the Initial Project Survey (IRB Approval 9-12-18 #008).

The data will be compiled and analyzed for themes and trends and the results written for an invited journal article for Gifted and Talented International. The data and analysis will also be used to design a research and grant proposal to train a cadre of teachers by sharing the research with them, and supporting them in the creation of lessons, strategies, and practical ideas for meeting the needs of this unique and underserved population. The research and practical applications will be compiled and submitted for possible publication.

_____ **FULL BOARD** I (We) believe that this project exceeds the requirements for the **EXEMPTED** and **EXPEDITED** classifications, and therefore, must be reviewed by the **FULL BOARD** of the HSRB.

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HUMAN SUBJECTS REVIEW BOARD PART II: RESEARCH PROTOCOL

Continued

(Please answer the questions below.)

YES	NO		
_____	___X___	A.	Human subjects in the proposed research are involved in activities that exceed those described as exempt categories.
_____	___X___	B.	The proposed research activity will involve a special class of subjects. Examples would include: children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. Further examples may include: individuals with psychiatric, cognitive, or developmental disorders, substance abuses, and any other special category of individual who may not have the capacity to make a reasoned decision about participation.
⇒ ⇒ ⇒ ⇒ (please circle appropriate classes of subjects)			
_____	___X___	C.	The proposed research activity will involve an element of deception.
_____	___X___	D.	The proposed research activity will expose subjects to discomfort or harassment beyond levels encountered in daily life.
_____	___X___	E.	The subjects will be identifiable to anyone other than the researchers through records, responses or identifiers linked to the subjects.
_____	___X___	F.	The subjects could be at risk of criminal or civil liability, damage to employability or to financial standing, or undue embarrassment, if responses became known outside this research project.
_____	___X___	G.	The research deals with sensitive aspects of subjects' behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
_____	___X___	H.	The research involves the collection or study of existing data from sources

		not publicly available. (Existing data can be documents, records, pathological specimens or diagnostic specimens).
_____ X__	I.	The subjects will be video/audio taped.
__X_____	J.	The subjects are free to withdraw at any time without penalty.
_____ X__ N/A	K.	The research activities outlined in Part III have the written approval of the authorized official(s) in the school district and/or other agencies involved with this research (if applicable). (Attach copy).
__X_____	L.	All required forms and safeguards are included with Part III: Summary of Proposal. This includes questionnaires, research instruments, letters of consent, approvals from authorized officials, etc. <i>Included in this proposal:</i> <i>Survey Questions/Research Instrument</i> <i>Consent Statement</i>

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HUMAN SUBJECTS REVIEW BOARD PART III: SUMMARY OF PROPOSAL

Summarize the proposed project and procedures to which humans will be subjected. **Consent form(s), questionnaires, etc. must be attached.** The summary should include purpose(s), solicitation and number of subjects, data collection procedures, an explanation of how consent is obtained, procedures for maintaining confidentiality and any potential risks involved for the subjects. Explain the nature of any deception if it is part of the design.

(Attach separate sheets if additional space is required.)

1. Project Description

Describe the specifications and objectives of your research, the data collection procedures, and any features of the research design that involve special conditions or procedures for subjects.

This survey primarily targets past Ashland University graduate students from the Talent Development (Gifted Endorsement and MEd) program who completed EDIS 654, "Creativity for Teachers of the Talented" in the past 20 years.

The objectives of this research are to gain knowledge:

1) As to the lasting-term impact of AU's model of creativity training on graduate students' personal lives.

2) As to the lasting-term impact of AU's model of creativity training on the graduate students' teaching lives.

I will analyze quantitative answers for trends and determine themes within the qualitative responses. This analysis will frame the second phase of The Creativity Project, the literature and research review. The analysis of qualitative and quantitative data will also provide ideas/structure for planning the third (practical) phase of the project, which involves up to 20 Gifted Intervention Specialists in Ohio districts reading the literature review and research findings and writing for classroom applications of creativity to support the needs of students identified gifted in Creative Thinking Ability.

2. Subject Recruitment

- A. Explain how subjects will be recruited. Include sources from which they are recruited, where and how subjects will be first contacted, and recruitment techniques to be utilized.

Subjects will be recruited via Ashland University's Alumni Association record keeping ASK PAM, AMY, ALUMNI ASSOCIATION ABOUT THIS.

- B. Describe the sample size and characteristics of the subjects. Include age, gender, and/or racial/ethnic affiliations causing them to be included in the study population, institution status (i.e., patients or prisoners), and their general state of mental and physical health. Explain why it is necessary to use these particular population subgroups or special populations.

Since the Talent Development Education program's inception, approximately 4,000 graduate students have taken EDIS 654 and all who are connected with Ashland University's Alumni Services will be sent the survey link. The sample size will be approximately 300 individuals. Subjects will be education professionals, the majority between 24 and 65 years of age of sound mind and holding a minimum of a bachelor's degree and teaching certification.

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3. Confidentiality of Data

Explain how data will be secured and/or stored to safeguard the identifiable records of individuals. Include how long the data will be stored beyond the required 36 months and how the data will be destroyed.

No personal identifying information is collected. Data on the district type and respondent role in that district is collected, but no individual or district names are included. Paper/pencil surveys will be held by the researcher and securely locked in a cabinet. Online survey information will be secured with password protection.

4. Informed Consent Procedures

- A. How will the subject be informed of the nature of the investigation, the reasonably foreseeable risks, and the voluntary nature of his/her participation?

In writing (attach a written copy of this explanation)

Orally (attach a written copy of this explanation)

- B. Once the above information has been presented, will you obtain written consent from the subject (i.e., their signature) prior to their participation?

Yes (attach a copy of the written consent form)

No (attach a detailed justification for requesting waiver of written consent)

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- C. Are the subjects: (Check all that apply)

children

mentally disabled

prisoners

economically disadvantaged

pregnant women

educationally disadvantaged

other (please specify) K-12 school personnel (teachers, administrators, coordinators, counselors, psychologists)

Describe from whom consent will be sought and by whom permission will be granted.

Consent will be sought from adult professionals ages 24 to (approximately) 65, who will grant permission on behalf of themselves. No minors are involved in this study.

5. Risks to Subjects

- A. Describe in detail any immediate or long range risks to subjects that may arise from the procedures used in the study. Risks may be physical, psychological, social, legal, or economic. Indicate the precautions you have taken to minimize these risks.

No immediate or long range risks to subjects are anticipated as a result of this survey.

- B. Explain the nature of any deception if it is part of the research design.

No deception of any kind is part of the research design.

6. Benefits

Describe the anticipated benefits to subjects, field of study, and to society, from knowledge that may be obtained in this study.

Anticipated benefits:

- *Program director will gain insight into the effectiveness of the current Creativity course model, content and focus.*
- *The College of Education will gain insight into the effectiveness of the Talent Development Program and the impact of the specific creativity model on program alumni.*
- *The field of Gifted Education – especially within Ohio - will benefit from increased knowledge about servicing options of The Ohio Rule for identifying Creative Thinking Ability. There is a great deal of misunderstanding and confusion surrounding this component of The Rule, so more knowledge is very much needed.*
- *Teachers and school personnel will benefit from the eventual practical ideas created and (hopefully) published as The Creativity Project.*
- *Ashland University will continue to be viewed by K-12, higher education, and other intellectual institutions as a center for research and development in the field of Creativity and Creativity Education.*
- *Ashland University will reconnect with alumni from the Talent Development MEd and Endorsement programs to participate in this first (survey) phase and the third (practical applications) phase of The Creativity Project. In this way AU can determine how we might improve or extend our Talent Development Program offerings to continue serving this population through professional development and coursework.*
- *And finally, students identified gifted in Creative Thinking Ability – indeed, all students - will benefit through the education and support of their teachers as a result of this project.*

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EXAMPLE OF TYPICAL CONSENT FORM

(Parental Consent)

“Title of Research Study”

Dear _____:

The Department of _____ at Ashland University supports the practice of informed consent and protection for human subjects participating in research. The following information is provided for you to decide whether you will allow _____ to participate in the present study. You are free to withdraw _____ at any time.

Your child will be asked to play a game with another child with a disability in a room that has toys and books, and your child's behavior will be observed. One session will last approximately 25 minutes. We are interested in studying the interaction between children who develop methods for increasing the effectiveness of efforts to integrate children with disabilities into the regular education classroom.

Your child's participation is solicited but strictly voluntary. We assure you that your child's name will not in any way be associated with the research findings. The information will be identified only through a code number.

If you would like additional information concerning this study before or after it is completed, or have any issues or concerns, please contact one of us by phone or mail. Thank you very much for your time, and we appreciate your interest and cooperation.

Sincerely,

Name of investigator
Graduate Student
Phone No. (____) _____
Address _____
City, State, Zip _____

Name of Faculty Member
Professor
Phone No. (____) _____
Address _____
City, State, Zip _____

I have read and understand the information about "Title of Research Study." I give consent for my child to participate in this study. I understand that this consent is voluntary and can be withdrawn without penalty at any time.

Signature of parent or legal guardian

Date

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**EXAMPLE OF TYPICAL CONSENT FORM
(Participant Consent)**

"Gender Differences in Communication Strategies of
Pleasant and Unpleasant Feelings"

A. PURPOSE AND BACKGROUND

Messrs. Smith and Jones in Ashland University's Psychology Department are conducting a research study to help understand how men and women communicate pleasant and unpleasant feelings. You are being asked to participate in this study because...

B. PROCEDURES

If you agree to be in the study, the following will occur:

1. You will view two 15-minute videotapes; one will be of pleasant and the other of unpleasant content.
2. After viewing both videotapes, you will be asked to take part in a focus group discussion led by Smith and Jones. Everyone in this focus group will have viewed the tapes. During the focus group, you and other group members will be asked to discuss reactions to scenes in both tapes. An audiotape will be made of this discussion. This discussion is expected to last about thirty minutes.
3. You will respond to a questionnaire about your reaction to the videotapes. It should take approximately fifteen minutes to complete the questionnaire.
4. You will answer questions on a standard paper and pencil personality test. It should take about an hour to complete this test.

These procedures will be done...and will take a total time of about two and one-half hours.

C. RISKS/DISCOMFORTS

1. Some of the videotapes are likely to produce unpleasant feelings, but you will be able to stop watching at any time if you feel too uncomfortable
2. Some of the focus group discussion questions may make you uncomfortable or upset but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.
3. Confidentiality: Participation in research will involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will ask you and the other people in the focus group to use only first names during the

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group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussion private. Only Smith and Jones and their assistant will have access to your study records and audiotapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand how the differences in how males and females communicate pleasant and unpleasant feelings.

E. COSTS

There will be no costs to you as a result of taking part in this study.

F. PAYMENT

You will be paid \$20 for your participation in this study. If you decide to withdraw prior to study completion, you will receive \$10. You will be paid in cash immediately after you complete your participation in the study.

G. QUESTIONS

You have talked to Messrs. Smith and Jones, or the person who signed below, about this study and have had your questions answered. If you have further questions, you may call him/her at....

If you have any comments or concerns about participation in this study, you should first talk with the researchers. If for some reason you do not wish to do this, you may contact the Human Subjects Review Board, which is concerned with the protection of volunteers in research projects. You may reach the board office between 8:00 and 5:00, Monday through Friday, by calling or writing....

H. CONSENT

You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study, or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your present or future status as a [patient, student or employee].

If you agree to participate, you should sign below.

Date	Signature of Study Participant
Date	Signature of Person Obtaining Consent

Notes to Researcher:

- Research involving sensitive aspects of the subject’s own behavior:** The Procedures section should discuss in detail the kinds of sensitive questions that will be asked during interviews, in questionnaires, or in focus groups (i.e., you should specify that questions about sexual activity, drug or alcohol use, domestic violence or child abuse, or other illegal activities will be asked).

In studies in which you think it is likely that subjects will reveal actions that you are legally or morally obligated to report to authorities (e.g., when child, spousal, or elderly abuse is suspected), a statement should be added to the consent form's discussion of confidentiality, briefly saying that such circumstances may arise.

When questions about drug use or other illegal activities are involved, research subjects are placed at risk since research discussions and records do not enjoy the same legal privilege as medical records. In order to protect your subjects better, you may wish to obtain a Federal Certificate of Confidentiality through your funding agency. This Certificate prevents courts from compelling researchers to reveal information about their subjects. Whether or not you obtain a Certificate, subjects should be warned in the consent form about the risk of loss of confidentiality. Wording like the following is recommended:

Participation in research will cause a loss of privacy. In this study you will be asked about drug use and other possibly illegal activities. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records.

If you obtain a Certificate of Confidentiality for the study, the end of the statement can be revised as follows:

...On rare occasions, research records have been subpoenaed by a court, but the National Institute on Drug Abuse [or other issuing agency] has given the researchers a Federal Certificate of confidentiality which says courts cannot force the researchers to reveal information about your participation in the study.

- 2. Collecting long-term tracking information:** If relatives, neighbors, co-workers, employers, or government agencies will be contacted during the study to provide information on subjects' whereabouts, you should explain so in Procedures. Subjects should be reminded that they could ask to have these tracking procedures stopped at any time.

RESEARCH PROPOSAL SUBMISSION CHECKLIST

The *Guidelines for the Conduct of Research Involving Human Subjects* outlines definitions and processes and should be reviewed in depth **prior** to submitting the research

proposal. The Appendix in the Guidelines contains the forms to be submitted to the Human Subjects Review Board.

All proposals will be screened using the following checklist. Incomplete proposals will be returned to the principal investigator, and the proposal will not be examined further. **Please examine the proposal carefully before submitting two copies of the proposal.**

- Complete information/signatures on page A-2

- Complete information on page A-3 including:
 - ❖ Type of review
 - ❖ Category(ies)
 - ❖ Explanation

- Written authorization attached (indicated by “yes” on item K on page A-4)

- Questionnaire(s) attached (indicated by “yes” on item L on page A-4)

- Project description included (item 1 on page A-5)

- Explanation of how subjects will be informed attached (see 4A. on page A-6)

- Written consent form or justification attached (see 4B. on page A-6)

- Verification of NIH or CITI training within 5 years from all investigators/faculty advisors attached (page A-1)